K063294

SECTION 9

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary

JAN 24 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 ad 21CFR 807.92.

Lossy Compressed Mammographic Images and Digitized Film Screen Images must not be reviewed for primary Image Interpretations. Mammographic Images may only be interpreted using an FDA approved Monitor that offers at least 5 Mpixel resolution and meets other specifications reviewed and accepted by FDA

I. General Information

Establishment:

Radiological Specialists, Inc.

Address: 5920 Noble Avenue, Van Nuys, CA 91411, U.S.A.

Phone: (818) 908-9000

Fax: (818) 908-9947

Registration Number:

Contact Person: Mr. Frank McMurray

President,

Phone: +1 (818) 908-9000

Fax: +1 (818) 908-9947

E_Mail: radspecinc@aol.com

Date of Summary Preparation: July 27, 2006

Device Name:

- **Trade Name:** *ToPACS*
- **Common Name:** Picture Archiving Communications System
- **Classification Number:**
  CFR 892.2050, System, Image Processing
- **Classification:** Class II
- **Performance Standards:**
  None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information.

- **Device Description:**

ToPACS is a stand-alone software package that is used on general purpose computing hardware. As long as minimum hardware requirements are met, the user or system integrator is free to choose his/her own hardware platform
The software allows digital image processing, measurement, communication and storage. ToPACS is tested according to the specifications that are documented in a Thoth PACS System Test Plan. Testing is an integral part of Thoth software development process. The software does not contact the patient, nor does it control any life-sustaining devices. A physician has ample opportunity for competent human intervention while interpreting images and clinical information.

- **Intended Use:**

The Thoth ToPACS is an image management system whose intended use is to provide (scaleable) DICOM compatible PACS solutions for hospital and related institutions/sites, which will archive/ distribute/ retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR and other devices) and information systems.

- **Technological Characteristics (comparison with predicate device):**

- **Predicated Device:**

k030781: KODAK DirectView 5
k023460: PACSPLUS
k031562: Ramsoft PACS

- **Statement of Substantial Equivalence:**

Thoth ToPACS is substantially equivalent to RamSoft PACS, PACSPLUS, and Kodak DirectView PACS. The determination of substantial equivalence is not based on an assessment of performance tests. It is our conclusion that there is no software component in ToPACS product or hardware component which would be used in conjunction with ToPACS product that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus, the "Level of Concern" of ToPACS product is "minor."

- **General Safety and Effectiveness Concerns:**

ToPACS does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Frank McMurray
President
Radiological Specialists, Inc.
5920 Noble Avenue
VAN NUYS CA 91411

JAN 24 2007

Re: K063294
Trade/Device Name: ToPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 1, 2006
Received: November 8, 2006

Dear Mr. McMurray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 6

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063294

Device Name: *ToPACS*

Indications for Use Statement:

The Thoth ToPACS is an image management system whose intended use is to provide (scaleable) DICOM compatible PACS solutions for hospital and related institutions/sites, which will archive/ distribute/ retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR and other devices) and information systems.

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CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

Prescription Use ✓

David G. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063294